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I wrote this almost 30 years ago for the now-defunct weekly Montreal paper *Hour*. It ran as the cover story of the May 23-29, 1996 issue. (Vol. 4, No. 21)

## **BAD MEDICINE, GOOD BUSINESS**

**By Maxine Ruvinsky**

Mammograms hurt so bad that for many women, once is enough. The suspect breast is flattened between horizontal plates, the clamp is tightened. The technician says, "Don't breathe," disappears behind a lead shield, then returns to repeat the procedure, now crushing the offending breast between vertical plates.

The pain factor is crucial, says Dr. Roger Landefeld, of Marion, Ohio, who estimated that half the women he sent for mammograms were so negatively impressed they never consented to a second. So when Landefeld--a trustee of the Ohio division of the American Cancer Society and a firm believer in the value of early disease detection--learned of a technology that didn't hurt, didn't pose a radiation risk, that tests had shown more sensitive than mammography, and that he could operate in his own office, he shelled out \$70,000 for a unit.

Called Lintro-Scan, the device uses infrared light and a video monitor to detect and display tumors or other abnormalities in the breast without exposing the patient to X-rays. A 1986 study at the University of Miami School of Medicine gave the Lintro-Scan a sensitivity rate of 96-per-cent, compared to 85 per cent for mammograms.

Landefeld began using the Lintro-Scan in September 1991. He was delighted with the results: Lintro-Scan detected at least two cancers (out of 180 tests) that were missed by both mammography and physical exam, and in one case, by biopsy as well. He even ended up doing a Lintro-Scan for one Montreal woman who travelled to his office after reading a Canadian Press story on Lintro-Scan in December 1992.

"Her health insurance wouldn't cover it because it was out of country--I did it for her for nothing," Landefeld said. And he would still be using Lintro-Scan today if not for a one-way run-in with the steamrolling FDA.

The U.S. Food and Drug Administration had approved Lintro-Scan only as an adjunct or aid to mammography. When it learned that some physicians were using it in place of mammograms, the FDA came down hard, seizing machines.

"Lintro-Scan is no longer on the market in the USA," Sharon Snider, FDA spokeswoman, said in a recent phone interview from the FDA's Washington press office. Snider confirmed that the FDA had seized Lintro-Scan machines. "It's not approved," she said. "It hasn't been shown effective for mammography purposes."

Mary Hessler, a former president of Lintronics Technologies Inc., the Tampa, Florida-based company that developed the technology in 1986, said the FDA shut down the company and its production facility in early 1993. "They told me it would be considered illegal to sell it in the U.S.," Hessler said.

The powerful government agency seized Landefeld's unit in March 1993, after he'd used it for eighteen months.

"They came into my office and threatened me if I didn't stop using it. . . They just showed up at my office," he said, outrage echoing in his voice. It was "two FDA field agents out of Columbus, that's all I know." They carted away his Lintro-Scan unit. No questions asked, no explanation--or compensation--offered.

Can the FDA do that?

"The FDA is omnipotent," said Landefeld, who blames the affair on vested interests. "It's about \$110,000 a (mammography) unit--that's a lot of money to throw away," Landefeld said. "I really think a lot of it had to do with the fact that Lintro-Scan would have put mammography out of business for the most part."

But shouldn't it?

"Exactly. It's very sad."

Landefeld says he's "gotten over most" of the Lintro-Scan affair. As for his patients: "I'm back to mammograms. I have no choice."

Most doctors have never even heard of Lintro-Scan.

Prominent Montreal breast cancer specialist Dr. Richard Margolese is a case in point.

"Never heard of it," Margolese said in a recent interview.

He suggested, however, that "it's useless, just another light-scanning machine. . . I remain convinced they don't find cancers smaller than mammography (does)."

Margolese was initially incredulous about Landefeld's experience. Informed that the FDA press office in Washington had confirmed its seizure of Lintro-Scan units, he turned even more incredulous.

"It just can't be that the FDA is a slave to vested interests," Margolese said. "They don't just seize machines capriciously," he added, suggesting that the powerful government agency must have had good reason for its pre-emptive action.

What about the radiation risk with mammography, and the concern that mammograms may be causing more cancer than they're detecting?

"That's ridiculous," Margolese said. "The radiation risk is less than trivial. . . This is a fraud."

In response to Landefeld's contention that the suppression of Lintro-Scan is a matter of money, Margolese concluded: "What a terrible thing to say."

Terrible indeed. And what if it's true?

Substantial funds are invested in mammography. A 1989 survey (published in Diagnostic Imaging magazine) showed there were 11,000 mammography units in the U.S. Most centres perform hundreds of mammograms a month at an average cost of \$100 each. That adds up to billions of dollars in mammogram fees alone, not counting even up-front profits for companies like General Electric that manufacture the machines or like Kodak, a major producer of mammographic film.

Frank Wiewel, head of People Against Cancer, a patient advocate group in Otho, Iowa, was well up on the Lintro-Scan saga. "Sure, I've heard of it," Wiewel said. "It's more sensitive and more selective than mammography. There's been some attempt to use it. . . The FDA has confiscated machines. Radiation oncologists and radiologists are essentially against it because it represents a competitive interest."

He had no trouble believing Landefeld's story.

"Yup," said Wiewel. "That's the way it is in the land of the free and the home of the brave."

Is the whole business simply a matter of money then?

"That's just exactly what it's about. . . This doctor in Miami used it and did a study on it and published it and his colleagues came to him and said that he must use it together in a program with mammography. So he was forced

to use mammography because they viewed Lintro-Scan as a competitive interest that was one, safer; two, more effective; and three, potentially damaging to the bottom line if patients found out about it.”

Sharon Batt, journalist and author of the ground-breaking *Patient No More*, calls herself “a bit of a screening skeptic.”

“Sure it would be great to have better screening, but it raises the question: What’s the use of better screening, when treatments remain ineffective?”

That mammography may cause more cancer than it detects is a valid concern, Batt said. “Especially with the new genetic research, which shows some oncogenes (genes that indicate predisposition to the disease) are particularly sensitive to radiation, such as the A-T gene.” (Women with a family history of breast cancer, who would be most likely to have regular mammograms, would thereby unknowingly raise rather than lower their risk of incurring a radiation-induced cancer.)

The worst, says Wiewel, is that “mammogram isn’t prevention at all, it’s diagnostic, and in fact isn’t benign. Canadian studies showed increased cancer risk (from mammography).”

Wiewel was referring to the National Breast Screening Study, a \$17-million effort funded mainly by the Canadian Cancer Society and the federal government. Begun in 1980, it tested almost 90,000 Canadian women between 40 and 59 over a seven-year period. The study found that routine mammograms missed 40 per cent of breast cancers in women aged 40 to 49. And it concluded that while annual mammograms allow earlier detection of breast cancer, they do not lower death rates from the disease.

“That’s why there was such a terrible fight over the results,” Wiewel said. “They were extraordinarily unwelcome to the medical establishment.”

Those attempting to discredit the study “talked about the old mammography machines, suggesting they’re much safer now--all this crap. This was technology that was being used by these physicians at the time, causing more cancers than they were finding. And there’s no evidence of a safer situation now.”

Following the release of study results in 1992, the Quebec Association of Radiologists called a news conference in Montreal to reject the study’s findings, and it worried out loud that “a study like this could convince people of limited means to forgo mammograms.”

The University of Toronto’s Dr. Anthony Miller, the study’s head researcher, defended the results and cut to the heart of the matter: “People make the

assumption that simply finding cancer early is in itself a good thing, but our study challenges that assumption.”

Ironically, while experts slogged it out in the mainstream media over the unwelcome findings, Lintronics Technologies was quietly preparing to market Lintro-Scan in Canada. According to Health Canada, a device prohibited in the U.S. is not automatically banned here. In fact, the now-defunct Lintronics had received permission to market Lintro-Scan in Canada.

That Lintro-Scan remains illegal in the U.S. and unavailable here “is ridiculous,” says Wiewel, “because the justification for mammography has always been that there was nothing better available. Lintro-Scan fell by the wayside in a bureaucratic war. The casualties are the patients.”

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